Express Mail Mailing Label No. EV 689994783 US Application Serial Number Filing Date April 24, 2001 Modell First Named Inventor 3737 Group Art Unit **NSMITTAL** Examiner Name Smith, Ruth S. **FORM** Attorney Docket No. MDS-009CN Not applicable Patent No. Not applicable Issue Date ENCLOSURES (check all that apply) Notice of Appeal to Board \boxtimes Copy of Notice to File Missing Fee Transmittal Form of Patent Appeals and Interferences Parts of Application ☐ Check Attached Appeal Brief (in triplicate) Formal Drawing(s) Copy of Fee Transmittal Form Request For Continued Status Inquiry Amendment/Response Examination (RCE) ☐ Preliminary Transmittal \boxtimes Return Receipt Postcard After Final Affidavits/declaration(s) Power of Attorney Certificate of First Class Mailing Letter to Official (Revocation of Prior Powers) under 37 C.F.R. 1.8 Draftsperson including Drawings Certificate of Facsimile Terminal Disclaimer [Total Sheets ____] Transmission under 37 C.F.R. 1.8 \boxtimes Additional Enclosure(s) **Executed Declaration and Power** Petition for Extension of (please identify below) of Attorney for Utility or Design Time Patent Application Pre-Appeal Brief Request for Review Information Disclosure **Small Entity Statement** Comments on Pre-Appeal Brief Request for Review Statement Check in the amount of \$250.00 Form PTO-1449 Copies of IDS CD(s) for large table or computer Citations program Amendment After Allowance Certified Copy of Priority Document(s) Request for Certificate of Sequence Listing submission Correction Certificate of Correction (in Paper Copy/CD Computer Readable Copy duplicate) Statement verifying identity of above SIGNATURE BLOCK CORRESPONDENCE ADDRESS Respectfully submitted, Patent Administrator Direct all correspondence to: Goodwin Procter LLP Exchange Place Date: November 22, 2006 Boston, MA 02109 William R. Haulbrook, Ph.D. Reg. No. 53,002 Tel. No.: (617) 570-1000 Attorney for Applicant(s) Tel. No.: (617) 570-1013 Fax No.: (617) 523-1231 Fax No.: (617) 523-1231 Goodwin Procter LLP

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PTO/SB/36 (07-05)

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Application Number	09/841,325	
Filing Date	April 24, 2001	
First Named Inventor	Modell	
Atty Docket Number	MDS-009CN	
Art Unit	3737	
Examiner	Smith, Ruth S.	

CERTIFICATE OF MAILING OR TRANSMISSION

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Signature Walle K. Hall				
Name (Print/Type)	Date	November 22, 2006		
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.				
This request is being filed with a notice of appeal.				
The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.				
I am the	2%	11-87/1		
☐ applicant/inventor	In	Signature Hersey		
☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)		William R. Haulbrook, Ph.D. Typed or printed name		
☑ attorney or agent of record Registration number53,002		617-570-1013 Telephone number		
attorney or agent acting under 37 CFR 1.34.				
Registration number if acting under 37 CFR 1.34.				
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representaive(s) are required. Sumit multiple forms if more than one signature is required, see below*.				

__ *Total of __

___ forms are submitted.



PATENT Attorney Docket No. MDS-009CN (120407/156456)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Modell et al.

CONFIRMATION NO.: 6590

SERIAL NO.:

09/841,325

GROUP NO.:

3737

FILING DATE:

April 24, 2001

EXAMINER:

Smith, Ruth S.

TITLE:

METHOD AND APPARATUS FOR SCANNING A BIOLOGICAL

SAMPLE

[title as amended 3/20/06]

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

COMMENTS ON PRE-APPEAL BRIEF REQUEST FOR REVIEW

This paper is submitted along with a Pre-Appeal Brief Request for Review in accordance with the Official Gazette Notice dated July 12, 2005, and a Notice of Appeal in response to the Office action mailed by the U.S. Patent and Trademark Office on August 24, 2006. A check for payment of the fee for filing the Notice of Appeal is submitted herewith. Applicants believe that no additional fee is required for this submission to be entered. However, please consider this a conditional petition for the proper extension, if one is required, and a conditional authorization to charge any related extension fee, or any other fees, necessary for entry of this submission to Deposit Account No. 07-1700.

Applicants' Remarks begin on page 2 of this paper.

REMARKS

The Examiner has improperly rejected all pending claims under 35 U.S.C. § 103(a). The Examiner fails to make prima facie rejections under 35 U.S.C. § 103(a). Specifically, a claim element that is clearly not present in applied art is not included in the Examiner's analysis.

Each of the pending independent claims 105 and 152 recites the limitation, "an internal biological sample, ... said sample not surgically exposed". The Examiner fails to show where this limitation allegedly appears in the cited art.

In the 8/24/06 Office Action, the Examiner alleges that U.S. Patent No. 6,424,852 . (Zavislan) teaches, "The tissue can be internal biological tissue as disclosed in column 7, lines 34-47." However, the Examiner does not allege anywhere in the Office Action that Zavislan teaches or suggests an internal biological tissue not surgically exposed. Furthermore, all of the rejections cite a combination of references, all including Zavislan.

Zavislan describes a device for examination of the <u>skin</u>. Zavislan does not teach or suggest "an <u>internal</u> biological sample, ... said <u>sample not surgically exposed</u>". Even if one could argue the few lines of **Zavislan** dealing with "internal tissues" (col. 7, lines 45-47) enables one to use its skin examination device to examine a surgically-exposed cervix (such surgical exposure being necessary, as admitted at lines 45-47 of **Zavislan**, given the device described therein), this would still not teach or suggest scanning "regions of an internal biological sample ... <u>said sample not surgically exposed</u>," [emphasis added] as recited in each of independent claims 105 and 152.

Applicants further point to arguments already of record in Applicants' Amendment and Response of December 23, 2004, at page 9-10.

According to the MPEP, to establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* MPEP, Eighth Edition, Rev. Oct. 2005, § 2143. Applicants submit that there is clear error in the Examiner's rejections and that the Examiner fails to establish a *prima facie* case of obviousness by not showing how the cited art allegedly teaches or suggests the claim element, "an internal

Comments on Pre-Appeal Brief Request for Review Application Serial No. 09/841,325 Page 3 of 3

biological sample, ... said sample not surgically exposed", which is common to both of the pending independent claims, claims 105 and 152.

Applicants respectfully assert that none of the cited art teaches or suggests the combination of elements recited in either claim 105 or claim 152, and that these claims are patentable in light of the cited art. Thus, all the dependent claims are patentable as well, at least for this reason, and a Notice of Allowance should be issued.

CONCLUSION

We respectfully submit that, as set forth in the foregoing remarks, there is clear error in the Examiner's rejections.

Respectfully submitted,

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